II. THE PHASE I SBIR AND STTR APPLICATION

Be sure to read the important changes and reminders in the first few pages of the SBIR Omnibus Solicitation. Read all instructions thoroughly. The language in the instructions has been carefully chosen. Too many applicants skim over these pages before plunging in, causing unnecessary problems during the review of their application.

The SBIR Phase I Omnibus solicitation including application forms is available on the Internet at **http://www.nih.gov/grants/oep/sbir/sbir962.htm** and may be downloaded in Adobe Acrobat Reader format. You may use an internet search engine to locate free Acrobat reader software that will enable you to view and print the application form. In addition, Delrina Form Flow application forms may be found at **http://min.com/air/magicc.htm**. The Delrina Form Flow program must be purchased to use these forms.

You may request a hard copy of the SBIR and STTR Phase I Omnibus Solicitations from:

NIH SBIR/STTR Solicitation Office	**Phone: (301) 206-9385**
13687 Baltimore Avenue	**Fax: (301) 206-9722**
Laurel, MD 20707-5096	**Email: a2y@cu.nih.gov**

Reminder: This guide contains both advice on preparing SBIR and STTR applications and summaries of most requirements. Rules, regulations, and general information are in regular type, and ***advice and commentary are in bold italics.***

Eligibility

Before going to the trouble of filling out an application, make very sure you are eligible for an SBIR or STTR award. Both SBIR and STTR applications MUST be submitted by a small business.

Company Requirements

To qualify for an SBIR grant, a business must:

- Be an independently owned, controlled, and operated for-profit U.S. business.
- Have a principal place of business in the U.S.
- Control the research facilities where the research will be conducted.
- Have 500 or fewer employees.

In addition to SBIR requirements, for an STTR grant, a business must:

- Be a partner with a research institution. At least 40 percent of the STTR work must be performed by the small business and at least 30 percent by the research institution (the

percentage is defined by cost unless otherwise justified in the contractual arrangements portion of the research plan).

A research institution is strictly defined. It is either nonprofit and owned and operated **exclusively** for scientific and educational purposes or a contractor-operated, federally funded research and development center. Other entities, such as laboratories staffed by federal employees (e.g., NIH and FDA) and nonacademic hospitals do not meet the requirements.

Principal Investigator Requirements

Both SBIR and STTR have requirements the PI must meet. For an SBIR grant, the PI must:

- Be employed more than half-time by the small business at the time of award and during the conduct of the project. There is no minimum requirement for percent effort by the PI ***but review committees expect a reasonable time commitment to the project.***

  Good news! This requirement is often possible for academicians in Phase I without loss in academic status or benefits. A PI can be employed almost 75 percent of his or her time by a university and still work over 50 percent for the small business. This works because a Phase I SBIR may last only six months. Fifty percent of six months means three months paid by the SBIR, leaving nine months, or about 75 percent of the calendar year, paid by the university.

For an STTR grant, the PI must:

- Devote at least 10 percent effort to the project.

- Have an official relationship with the small business applicant but not necessarily receive a salary. Do not include documentation about this in the application. The NIH Institute or Center (IC) will ask for documentation before the award is made.

Correct Application Form

Use the appropriate form. The SBIR Phase I form is PHS 6246-1, and the STTR Phase I form is PHS 6246-3. These forms differ significantly.

The SBIR **Fast-Track** application (see page 28) will use both the SBIR Phase I form (PHS 6246-1) and the SBIR Phase II form (PHS 6246-2). Contact the SBIR Solicitation Office listed on page 13 for the appropriate forms.

Receipt, Review, and Award Dates – Annual

Table 1. Important Dates

SBIR Application Receipt Date	STTR Application Receipt Date	Scientific Merit Review (Study Section)	Secondary Review (Advisory Council)	Earliest Award
Apr 15	Apr 1	Jun - Jul	Sep - Oct	Nov
Aug 15	Aug 1	Oct - Nov	Jan - Feb	Mar
Dec 15	Dec 1	Feb - Mar	May - Jun	Jul

The receipt date is the postmark date if sent by U.S. mail or the date that NIH receives the application if sent by other means. ***You probably will want proof of the mailing date and a return receipt request.***

Award Amount

The total cost (direct and indirect) allowed:

- SBIR Phase I $100,000; Phase II $750,000
- STTR Phase I $100,000; Phase II $500,000

Project Period

Project periods for Phase I vary for SBIR and STTR:

- SBIR - six months

  Don't make a common mistake! Though the Omnibus Solicitation states that "normally, the SBIR Phase I may not exceed six months," many applicants propose research that is overly ambitious for a six-month period. ***This error can seriously dampen reviewers enthusiasm. If you know that your proposed research will take longer than six months, consider requesting up to a year for Phase I, thoroughly justifying the longer time.***

- STTR - usually one year

Summary of Differences Between SBIR and STTR

Table 2. SBIR and STTR Comparisons

REQUIREMENTS	SBIR	STTR
Application form	PHS 6246-1	PHS 6246-3
Subcontracts including consultants	May not exceed 33 percent in Phase I or 50 percent in Phase II	Must subcontract at least 30 percent to academic partner; total of all subcontracts and consultants cannot exceed 60 percent
Principal Investigator requirements	Employed by company over 50 percent time during award	Minimum 10 percent effort on project
Time	Phase I - 6 months or more	Phase I - 1 year
Performance site	Must be entirely in U.S.; part of research must take place in company-controlled research space.	Must be entirely in U.S.; part of research must take place in company-controlled research space and part in that of academic partner.
Maximum award	Phase I - $100,000 Phase II - $750,000	Phase I - $100,000 Phase II - $500,000
Application dates	Apr 15, Aug 15, Dec 15	Apr 1, Aug 1, Dec 1

"Just in Time" Information for Phase I Applications

Several Phase I budget items, assurances, and other details previously required in SBIR and STTR applications are now required only when an application is selected for funding. In the solicitation instructions, these are marked "**Do not complete this item at the time of application**." Known as "Just in Time," this process decreases the burden of preparing applications.

Because successful applicants will have to provide this additional information prior to funding, i.e., "Just in Time," it is prudent to plan early for the information that will be requested.

The table below lists the information to be included in the application and information to be provided just prior to award. Advice follows the table.

Table 3. Information Needed in the Application or for Just in Time

INFORMATION	IN THE APPLICATION	JUST IN TIME
BUDGET ITEMS		
Personnel: Names, role on project, & percent effort.	X	
Type of appointment, institutional base salary, salary requested, fringe benefits, total.		X
Total personnel cost (labeled subtotals).	X	
Consultant costs – total cost only. If over $10,000 and/or consultants are identified as "Key Personnel" on the Abstract form, itemize and justify.	X	
Equipment – total cost only. If over $15,000, itemize and justify all items over $5,000.	X	
Supplies – total cost only. If over $15,000, itemize and justify categories of items over $1,000 and itemize number and kind of animals, unit purchase cost, and unit care cost.	X	
Travel – total cost only. If over $5,000, itemize and justify.	X	
Contractual costs – itemized.	X	
Other expenses – total cost only. If over $5,000, itemize and justify items.	X	
Fixed fee – justify.	X	

INFORMATION	IN THE APPLICATION	JUST IN TIME
OTHER ITEMS		
Other support.		X
Principal Investigator documentation. Eligibility for SBIR award if not full-time employee of company.	X	Updated letter(s).
Consultant letters of commitment.	X	
Letter from organization providing research space certifying grantee exclusive control (if applicable).	X	
Human subjects information on six required items.	If page 1, item 4 human subjects is checked yes.	
Institutional Review Board (IRB) approval and Office for Protection from Research Risks (OPRR) assurance for human subjects. You will obtain detailed instructions from OPRR if your award is likely. Call (301) 496-7005 for information.		X
Animal welfare information on five required items.	If page 1, item 5 is checked yes.	
Institutional Animal Care and Use Committee (IACUC) approval. An IACUC should be identified or established prior to the application.	Within 60 days of application receipt date.	
OPRR assurance for animal welfare. You will obtain detailed instructions from OPRR if your award is likely. Call (301) 496-7163 for information.		X
Drug-free workplace certification. **Delinquent Federal debt certification.** **Debarment & suspension certification.**	By signature on page 1 of application.	
Research misconduct assurance to the Office of Research Integrity (ORI).	By signature on page 1 of application.	Policy in place by award date; each year submit PHS Form 6349.

INFORMATION	IN THE APPLICATION	JUST IN TIME
Assurance of compliance (civil rights, handicapped individuals, age discrimination). For form or more information call (301) 594-7248 or fax (301) 594-7384.		Submit form HHS 690 to HHS Office of Civil Rights.
Indirect cost rate negotiation.	Not required for first Phase I award.	Prior to funding of first Phase II award.
Inclusion of women and minorities in research involving human subjects.	Put details in application.	
Program income (income earned by the recipient during the grant period as a result of activities supported by the grant).		Discuss with your Grants Management Officer.

Page Limitations

Reviewers appreciate comprehensive but succinct proposals. Do not exceed the 25 pages allowed for your Phase I application. Remember that appendices are **not** allowed.

Not counted in the 25-page limitation are:

- Cover letter.
- Introduction to a revised application limited to one page for Phase I
- Letters of commitment from collaborators and consultants.
- Letters to determine eligibility.
- Checklist page.
- Information on prior SBIR Phase II awards, if applicable.

Type Size

Applicants are often tempted to squeeze as much information as possible within the 25-page limit. However, you should avoid alienating reviewers with small, hard-to-read type. Besides, typesetting requirements are strictly enforced. Beware of the following minimum specifications:

- 10 point font size is the minimum allowed, ***but your application may be better received with 12 point font.***

- Density of letters must not be more than an average of 15 characters per inch ***but fewer may be better.***

- ***Do not squeeze lines together****;* no more than 6 lines per vertical inch are allowed.

- Type size in figures and tables may be smaller but must be readily legible.

Preparing a Budget

Tips for Preparing Your Budget

- ***Although budget pages come at the beginning of your application, you may wish to complete them after you have written your Research Plan and have a good idea of costs.***

- ***Almost all Phase I grants receive the maximum allotted $100,000 funding. However, always prepare a well-justified budget. This is particularly important for Phase II applications. Use continuation pages if you need more space. If you expect the Phase I research to cost over $100,000, indicate the amount and source of the additional funds separate from the budget page. Some reviewers are positively influenced by a company's commitment of resources to the project.***

- ***Reviewers evaluate a budget for whether it is realistic and justified by the aims and methods of the project.***

- ***Concisely describe the role of all staff, professional and nonprofessional, even when not requesting salary. Reviewers appreciate estimates of the time each person will work on each experiment or task. Make sure estimates do not exceed 100 percent.***

- ***You may wish to avoid purchasing expensive equipment. Reviewers will delete requested funds for equipment that appears to duplicate what should be available to you. Reviewers know that institutions own equipment purchased on grants, and some reviewers are not enthusiastic about Federal funding of equipment that will belong to the company. Consider rental if you need expensive equipment and thoroughly justify it. Or use a lease-purchase arrangement that enables you to purchase the equipment at a reduced cost at the end of the grant period.***

- ***Avoid expenses that might APPEAR to be extravagant such as unwarranted travel.***

- ***Thoroughly justify consultants. Describe exactly what tasks they will do and include a detailed, justified budget for their work.***

- ***You can request a reasonable fixed fee up to 7 percent of total costs but may wish to forgo this option. Some reviewers may be negatively influenced by a company receiving a fee in addition to NIH funding of research that benefits the company.***

The Salary Cap

- ***Make sure you calculated the PI's salary, taking into account the government cap of $125,000.***

  The salary cap can be a problem for highly paid scientists. For example, let's say a PI who makes $200,000 as a university physician scientist is devoting 10 percent effort to the SBIR. Accordingly, the university salary will be $180,000 (for a 90 percent effort). The PI may believe it is appropriate to charge the remaining $20,000 to the grant. Not so! The PI can charge only $12,500 (10 percent of $125,000) for his or her work on the SBIR grant.

Consultant Costs

- ***Careful selection and addition of consultants can add credibility to your application and greatly improve its quality. Remember to include letters from consultants stating that they agree to participate in the project and describing their specific roles. You may want to ask academic consultants to share their application experience with you.***

- ***Many SBIR and STTR applications benefit from statistical analysis. The early involvement of a statistics expert to determine the amount of data to collect and the methods for analyses will favorably impress reviewers.***

- Remember that the **total of SBIR consultant fees AND contractual costs** normally may not exceed 33 percent of Phase I and 50 percent of Phase II total costs.

Performance Sites

Research must be performed entirely in the U.S. Some of the research must be performed at the company site. If the company site is located in space belonging to another research organization (a landlord), a letter must be included from the landlord certifying that the SBIR or STTR-funded company controls its own research space. The capability of the company to conduct research at its site should be detailed in the Resources section of the application.

Resources

The Resources section of your proposal is a critical part of an SBIR or STTR application. Use continuation pages if you need more space to illustrate why your environment is outstanding.

- ***Show reviewers that the company has the equipment, space, support staff, and other necessary experience and facilities to conduct the research***.

- ***Don't assume that reviewers know your facilities have gas, vacuum, centrifuges, scintillation counters, gel apparatus, computers, autoclaves, shop, animal facilities, secretarial and financial support, or anything else you need for research***.

Biographical Sketches

This section is your chance to showcase the knowledge, skills, and abilities of the key staff and consultants involved in the project.

- ***Read the instructions carefully, and include what is required***. For each key professional listed on the page 2 Abstract (beginning with the Principal Investigator), include:

    1. Name, title, birth date.
    2. Education – institutions, location, degree(s), year conferred, and field(s) of study.
    3. Employment history in reverse chronological order – dates, places, nature of position, professional experience, honors.
    4. Publications, most pertinent in chronological order – titles and complete references.

- ***In addition, use the biographical sketch to indicate experience by describing specific roles in other ongoing or previously supported research.***

- ***Remember that the 25-page limit includes all biographical sketches***.

Research Plan

A top-quality research plan is the biggest factor determining your priority score. As with a scientific publication, developing your ideas is key. Think of "Specific Aims" as what goals you propose to achieve in Phase I, "Background and Significance" as why it is worth doing, and "Experimental Design and Methods" as how you will go about it.

Here are some tips for putting together a research plan:

- ***Present your research logically and clearly***.

- ***Highlight its importance and innovation***.
- ***Many reviewers believe strongly in hypothesis-driven research. Their enthusiasm for your application may increase if you can phrase your research in terms of testing a specific hypothesis. State your hypothesis in Specific Aims and in the Abstract.***

- ***Be sure your project has a coherent direction***.

- ***Keep the sections of the Plan well coordinated and clearly related to a central focus.***

- ***Follow the format in the instructions. Reviewers expect the Research Plan to be organized exactly as described in the instructions – you do not want to upset these expectations! Label sections exactly as in the instructions:***

    A. Specific Aims
    B. Significance
    C. Relevant Experience
    D. Experimental Design and Methods
    E. Human Subjects
    F. Vertebrate Animals
    G. Consultants
    H. Contractual Arrangements
    I. Literature Cited

- ***Explain what gaps in science and/or commercialization your project would fill.***

- ***Refer to the literature thoroughly and thoughtfully but not to excess***.

  Research proposals typically do not fare well when applicants are unaware of relevant published work, products, or services or when the proposed research or study design has already been tried and judged to be inadequate.

- ***Where appropriate, include well-designed tables and figures. Use titles that are accurate and informative. Label the axes and include legends. Reviewers will look for discrepancies between what you show and what you describe in your proposal. Be sure you explain the details, or reviewers may see things differently than you do.***

- ***Edit and proofread thoroughly. Look carefully for typographical and grammatical mistakes, omitted information, and errors in figures and tables. Sloppy work will definitely suffer in review.***

- ***Have your colleagues review the application. They can help point out unclear statements and other potential problem areas such as typographical errors, omitted***

figures, absent biographical sketches, missing letters, confusing budget justifications, and items you missed.

- ***If you cannot meet the application deadline comfortably, consider delaying to the next receipt date.***

Writing Tips

Use a clear, concise writing style. Here are a few pointers:

- ***Use the active rather than passive voice. For example, write "We will develop a cell line," not "A cell line will be developed."***

- ***Keep related ideas and information together, e.g., put clauses and phrases as close as possible to - preferably right after - the words they modify.***

- ***Simplify and breakup long, involved sentences and paragraphs. In general, use short simple sentences; they are much easier on the reader. Your goal is communication, not literature.***

- ***Edit out redundant and awkward words and phrases.***

- ***Have someone with good writing skills read your application. Also, having another person who is not familiar with your work read your application is an excellent way to make sure your writing is crystal clear.***

Prior SBIR Phase II Awards

If your company has received more than 15 Phase II SBIR awards during the previous five fiscal years, you must include the following information in the application for each award:

1. Name of awarding agency
2. Award number and date
3. Amount of award
4. Title of project
5. Source, date, and amount of Phase II funding agreement(s)
6. Commercialization status of each Phase II award

Introduction to Revised Applications

You must include an Introduction (limited to one page and not counted in the 25-page limitation) if you are submitting a revised application. Help reviewers understand your revisions by following the instructions. In one page, summarize any substantial additions,

deletions and changes, and respond to criticisms in the previous summary statement. Clearly distinguish those sections that are the same in the previous application and those that are different. For example, you may choose to indent, bracket, underline, or change the type of revised text.

Title, Abstract, and Specific Aims

Write these three sections carefully. The NIH referral officer depends heavily on these items to assign your application to a peer review panel and to an IC (Institute or Center). Clarity in these sections will help direct your proposal to appropriate primary reviewers and may encourage other reviewers in the study section to read it.

- ***Make your Title specific and detailed within the 56-space limitation.***

- ***Write your Abstract last. Make it a clear, succinct summary of your Phase I proposal within the 200-word limit. If you can't express a clear idea in 200 words, it is unlikely that the theme will bloom into a well-thought-out project in 25 pages.***

  State your long-term commercial objective, why it is important and innovative, plans and methods for accomplishing Phase I goals, potential problems and solutions, and a brief discussion of plans for Phase II and III. Remember, if funded, the Abstract becomes public information.

- ***Your Specific Aims should be measurable objectives you intend to complete by the end of Phase I. Choose objectives that can be easily assessed by the review committee for your Phase II application. Do not confuse Specific Aims with your long-term goals for a product.***

Limit the Scope of Your Proposal

Remember that the purpose of Phase I according to the Omnibus Solicitation is " . . . to establish the technical merit and feasibility of the proposed research . . . prior to providing further federal support in Phase II." ***The solicitation does not say "feasibility of producing the product."***

For most products, feasibility must be assessed at many R&D steps from the initial inception of an idea to eventual sales. For example, the development of a drug may require feasibility determinations at multiple stages: in vitro studies, tissue culture studies, toxicology, safety and efficacy studies in animals, and clinical trials.

The *Omnibus Solicitation* states "Phase II grant awards are nonrenewable, and only one Phase II award may be made for any SBIR project." ***The solicitation specifies "SBIR project" not "SBIR product." Thus, the window is open for more than one SBIR Phase I***

or II grant for any product. But you will have to carefully define and limit your Phase I and Phase II projects. And you will have to admit that you will be only part way along the path to a product by the end of the first Phase II. Discuss your plans with your Program Officer.

Significance

Describe how your research is innovative and will lead to a significant commercial product or service.

Innovative means new technologies, significant improvement of existing technologies, or development of new applications for existing technologies.

Keep it brief. If the significance is not readily apparent to reviewers, you may want to reconsider the proposal.

Relevant Experience

Describe your previous experience and present preliminary data. To be competitive with other applications, the PI and staff should show experience in the proposed research as demonstrated by publications, patents, or similar products.

NOTE: ***Although preliminary data is not required for a Phase I application, those with considerable preliminary data indicate to reviewers that the proposal has a high probability of success. These applications are likely to score better than applications containing only good ideas.***

Experimental Design and Methods

Organize this section parallel to your specific aims. Describe in detail the experimental design and procedures to accomplish the specific aims. While you may assume reviewers are experts in the field and familiar with current methodology, they will not make the same assumption about you.

It is not sufficient to state, "we will grow a variety of viruses in cells using standard in vitro issue culture techniques." Reviewers want to know which viruses, cells, and techniques; the rationale for using the particular system; and exactly how the techniques will be used.

The burden of proof is on you. You must show through a clear, succinct, detailed explication that you understand and can handle the research.

Call attention to possible problems! Discuss potential difficulties and limitations of your proposed procedures, and propose solutions to them. Since reviewers are experienced

research scientists, they will be aware of possible problems. They have no way of knowing that you have considered these problems unless you address them.

Discuss the criteria for determining whether feasibility has been demonstrated.

Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions you will take.

Research Involving Human Subjects

When research involves people or samples from people, it must be approved by an Institutional Review Board (IRB) prior to funding unless it is exempt. See *Omnibus Solicitation* instructions for six categories of research exempt from human subject review and call your Program Officer for any questions you may have.

Review the instructions on assurances and certifications for what to send to NIH and when to send it (see *Omnibus Solicitation* instructions for Research Plan, E. Human Subjects). IRB approval is not required at the time of application, ***but you should start the process early because revisions and final approval can take time.*** Before an application is funded, you must file an Assurance of Compliance with the Office for Protection from Research Risks (OPRR). Read the instructions, and call OPRR at (301) 496-7041for details and help.

Your application MUST provide information on these six items:

1. Characteristics of the subjects. ***Be sure to ensure adequate representation of minorities and both genders. Any exclusions must be justified***.
2. Sources of research materials.
3. Recruitment plans and consent procedures.
4. Potential risks.
5. Procedures for protecting against or minimizing potential risks.
6. Potential benefits to the subjects and to mankind.

If you fail to include this information, your application may be deferred. ***Include enough information so reviewers have no questions about what you propose to do.***

Research Involving Vertebrate Animals

If the proposed research involves vertebrate animals, your project must be reviewed and approved by an Institutional Animal Care and Use Committee prior to funding.

You will also need an animal welfare assurance identification number (see instructions – Research Plan, item F. Vertebrate Animals).

In the application, you MUST provide information pertaining to the following five items described in the instructions (see Research Plan, F. Vertebrate Animals). If you fail to include this information, your application may be deferred.

1. A detailed description of the proposed use of the animals.
2. A justification for the choice of species and number of animals to be used.
3. Information on the veterinary care of the animals.
4. An explanation of procedures to ensure that the animals will not experience unnecessary discomfort, distress, pain, or injury.
5. Justification for any euthanasia method to be used.

Appendices Not Allowed in Phase I

Do not include appendices, separate pictures, or devices in Phase I applications.

Literature Citations

Do not list references in the body of the text; place them at the end of the Research Plan in a section titled "I. Literature Cited". Each citation must include the names of all authors (not *et. al.)*, name of book or journal, volume number, page numbers (not first page only), and year of publication. ***Also, the list of citations should be relevant and current and need not be exhaustive. Padding this list with repetitious or out-of-date entries will not impress reviewers.***

Fast-Track SBIR Applications

With an innovation called "Fast-Track," NIH will be testing out an innovative review approach for SBIR applications: evaluating Phase I and II at the same time. New procedures illustrated in **Figure 5** will speed up the review and award of Phase II funds for qualifying SBIR applications and will eliminate the troublesome between-phases funding

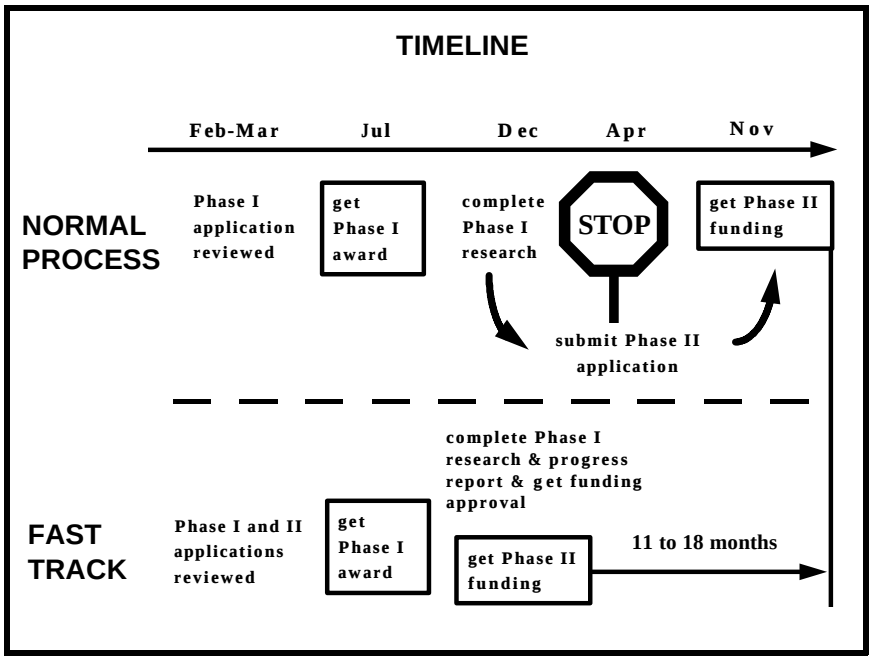

Figure 5. Fast Track Advantage

gap that has plagued many a grantee.

Fast-Track is intended for high-quality applications with sufficient preliminary data to delineate "go – no go" milestones for the next two to three years. BEWARE, if your application does not meet or exceed the stringent Fast-Track requirements, you will probably be better off submitting your application under the standard SBIR Phase I pathway!

Fast-Track is a parallel review option that offers two advantages over the regular SBIR review mechanism:

- Single submission and evaluation of both Phase I and Phase II applications.
- Potential for minimal or no funding gap between Phase I and Phase II.

To be eligible for Fast-Track, applications must satisfy three additional criteria:

- The Phase I application must include measurable milestones that will be used to judge the success of the Phase I research. In place of a progress report, the Phase II application must include a discussion of the Phase I milestones and their implications for Phase II.
- The Phase II application must be accompanied by a **Commitment Appendix** that specifies the amount of company, partner, or other funds or resources to be dedicated to activities directly related to the SBIR project and must describe those activities. Because of the risk involved, the partner's commitment(s) may be contingent upon the small business concern receiving the Phase II award, achieving technical objectives, and the technology continuing to be scientifically and economically viable in the marketplace. Details of commitment contingencies must be described.
- The Phase II application must be accompanied by a concise **Product Development Plan Appendix** (limited to five pages) addressing each of the following areas:
    - Company information, including size; specialization area(s); products with significant sales; and history of previous Federal and non-Federal funding, regulatory experience, and subsequent commercialization.
    - Value of SBIR product, including a lay description of key technology objectives, current competition, and advantages over competing products or services.
    - Commercialization plans, milestones, target dates, analyses of market size, and estimated market share after first-year sales and after five years.

- Patent status or other protection of intellectual property.

The Fast-Track pilot is being conducted by the following ICs as part of NIH's reinvention effort:

National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Cancer Institute (NCI)
National Institute of Child Health and Human Development (NICHD)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of General Medical Sciences (NIGMS)
National Heart, Lung, and Blood Institute (NHLBI)
National Institute of Mental Health (NIMH)
National Center for Human Genome Research (NCHGR)

Before submitting a Fast-Track application, contact the Program staff named below for specific details relevant to that IC.

Table 4. Fast-Track Staff Contact List

Component	Staff Contact	Phone	Email
NIAAA	Dr. Laurie Foudin	(301) 443-4224	lf29z@nih.gov
NIAID	Dr. Gregory Milman	(301) 496-8378	gm16s@nih.gov
NCI	Ms. JoAnne Goodnight	(301) 496-5307	jg128w@nih.gov
NICHD	Dr. Danuta Krotoski	(301) 402-2242	dk58p@nih.gov
NIDDK	Mr. John Garthune	(301) 594-8842	jg60d@nih.gov
NIEHS	Dr. Michael Galvin	(919) 541-3843	mg63c@nih.gov
NIGMS	Dr. Michael Martin	(301) 594-3910	mm72k@nih.gov
NHLBI	Dr. John Watson	(301) 435-0513	jw53f@nih.gov
NIMH	Dr. Michael Huerta	(301) 443-5625	mh38f@nih.gov
NCHGR	Dr. Carol Dahl	(301) 496-7531	cd41x@nih.gov